

### REMARKS

Claims 6, 8, 21, and 22 are cancelled. Claims 1-5, 7, 9-20, and 23-27 are pending in the application. Claims 1-4, 7, 9, 15-20, and 23-27 are rejected. Claims 5 and 10-14 are objected to.

#### Amendment transmitted 25 May, 2005

With regard to the Office Action mailed December 01 2005, Applicant requests clarification of the Response to Amendment/Arguments. Applicant amended Claims 1, 2, 9, 15, 17, 18, 21, 22, and 25-27 in response to the Office Action mailed 08 February 2005. No such amendment to the Claims is acknowledged by the Examiner, nor are reasons given for any amendment being non-persuasive. Applicant respectfully inquires whether the Examiner received and considered the amendment to the claims submitted 25 May 2005.

Claims 1, 7, 9, 15, 23, and 26 have been amended in response to the Office Action mailed 01 December 2005. Support for the amendments to the claims may be found throughout the specification, especially on page 5 [13], page 11 [38], Figures 1, 4, and 5, and the claims as originally filed. Reconsideration of the application based on the remaining claims as amended and the arguments submitted below is respectfully requested.

#### Claim Rejections - 35 U.S.C. § 102(b)

Claims 1-4, 6, 9, 15, 17, 18, and 20-27 have been rejected under 35 U.S.C. §102(b) as being anticipated by Braithwaite (U.S. Patent No. 6,347,629). Applicant respectfully requests that these rejections be withdrawn in consideration of the amendment to the claims and the following arguments.

Braithwaite does not disclose an inhaler spacer comprising a linear spray conduit from the spray inlet to the mouthpiece.

Claims 1, 9, 15, 23, and 26, as amended, recite the limitation of a linear spray conduit. The Braithwaite patent discloses a dry powder inhaler having a mouthpiece with a cyclonic chamber that causes air and powder delivered by the inhaler to swirl toward the outside walls of

the mouthpiece. The Braithwaite invention requires non-linear flow of drug particles to function and does not teach or suggest an inhaler spacer having a continuous, linear spray conduit.

Braithwaite does not disclose a plurality of inlets passing through the first body to allow external air to pass into the first body.

With respect to Claim 2 as originally filed, the Examiner asserts that Braithwaite “*teaches a spacer further comprising a plurality of air inlets 90 passing through the first body, the air inlets positioned downstream from the spray inlet near the distal end of the first conical body.*” The relevant description in Braithwaite (Column 8, lines 65-67) states; “*In this manner there are formed spiral passageways 90 leading from the inhaler mouthpiece 92 to a cyclone chamber 100...*” Thus, the passageways 90 connect the flow of drug from the inhaler mouthpiece to cyclone chamber. Braithwaite does not disclose any air inlets.

Claims 2, 9, 17, and 23 were amended in response to the Office Action mailed 08 February 2005 to recite the limitation of air inlets that allow *external* air to pass into the spacer. Paragraph 36 of the present specification states that “*air inlets*” allow “*external air to pass into the first chamber.*” The “*air inlets*” of the present invention have different structures from and serve different functions than the “*passageways*” of Braithwaite.

With respect to Claims 17, 20, 25, and 27 and as explained in arguments to the rejection of Claim 2, 90 in Figure 9 of Braithwaite is disclosed as being a passageway “*leading from the inhaler mouthpiece 92 to a cyclone chamber*” and not an air inlet that allows external air to pass into the first chamber.

Braithwaite does not disclose or suggest recirculation zones functional to inhibit contact between the medication spray and the spacer walls.

Claims 23-27 recite recirculation zones functional to inhibit contact between the medication spray and the spacer walls. Braithwaite discloses a device that receives powder from an inhaler and generates centrifugal forces (i.e. toward the outer walls of the chamber) to separate lighter particles from heavier ones. The heavier particles are directed into the walls of the chamber, not away from them (column 3, line 44 through column 4, line 1). Consequently, the Braithwaite does not anticipate claims 23-25.

The examiner asserts that Braithwaite teaches “...*spacer geometry to generate high-pressure recirculation zones at 100,101 inside the spacer; and using the high-pressure recirculation zones and external airflow to direct the medication spray away from the walls of the spacer and out of the mouthpiece end of the spacer.*”

Braithwaite does not disclose any external airflow into the cyclonic chamber, only flow from the inhaler. Braithwaite refers to negative pressure but does not mention positive pressure forces. The centrifugal airflow in the Braithwaite device is specifically designed to prevent the inhalation of large particles by directing them into the walls of the air circulation chamber (Figs. 2, 7, and 8). The summary of the invention in column 2 clearly states that the purpose of the Braithwaite invention is to PREVENT heavier particles from reaching the outlet of the device. Unlike the present invention, the Braithwaite device is designed to cause contact between medication spray and the spacer wall and not inhibit contact between medication spray and the spacer wall.

Claim Rejections - 35 U.S.C. § 103(a)

Braithwaite does not teach or suggest an inhaler spacer comprising a linear spray conduit.

Claims 7, 16, and 19 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Braithwaite (U.S. Patent No. 6,347,629). Applicant respectfully requests that these rejections be withdrawn in consideration of the amendment to the claims and the following arguments.

Claim 1, from which Claim 7 depends, has been amended to recite “...*first and second internal chambers forming a linear spray conduit having a continuous spray passage from the spray inlet to the mouthpiece.*” Claim 15, from which Claims 16 and 19 depend, has been amended to recite “...*a linear internal spray path....*” Braithwaite does not disclose or suggest a linear spray passage. Consequently, Applicant respectfully requests that the rejection of claims 7, 16, and 19 under 35 U.S.C. §103(a) as being unpatentable over Braithwaite be withdrawn.

The geometry and airflow of the present device are not obvious design variations of Braithwaite.

The Examiner's asserts that *"it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the shape of the bodies and air inlet of Braithwaite of any particular geometric shape,"*

The Braithwaite device and the present invention are designed to achieve different aims through different and incompatible designs. The Braithwaite device is intended to prevent inhalation of large dry powder particles by directing them to impact with the walls of the cyclonic chamber. The effect of the Braithwaite device is to prevent a portion of the medication dispensed by a dry powder inhaler from entering the patient's mouth.

The present invention prevents the impact of medication dispensed by a metered dose inhaler on the walls of the spacer. The effect of using the present invention is to deliver all of the drug dispensed by the inhaler to the mouth of the patient and to increase the amount of drug entering the lungs of the patient.

The Examiner asserts that *"the Applicant has not disclosed that the specific geometry provides an advantage, is used for a specific purpose, or solves a stated problem."* The Examiner also states that any shape would work equally well and would perform the same function *"of reducing the particle size of the medicament and providing a passageway for air."* Applicant refers the Examiner to paragraphs 14, 40-43, 48, and 49 in the present application in which the importance of the geometry and external airflow patterns of the present invention, as well as their advantages over other geometries, are described.

Applicant respectfully requests that the rejections of Claims 7, 16, and 19 under 35 U.S.C. § 103(a) be withdrawn.

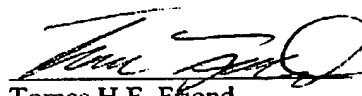
#### Allowable Subject Matter

Claims 5 and 10-14 have been objected to as being dependent on a rejected base claim but have been deemed allowable if re-written in independent form to include all of the limitations of the base claim and of any intervening claims. At the present time, Applicant has not amended these claims to independent form because Applicant believes that the base claims are allowable for the reasons stated above.

Applicant has commented on some of the distinctions between the cited references and the claims to facilitate a better understanding of the present invention. This discussion is not

exhaustive of the facets of the invention, and Applicant hereby reserves the right to present additional distinctions as appropriate. Furthermore, while these remarks may employ shortened, more specific, or variant descriptions of some of the claim language, Applicant respectfully notes that these remarks are not to be used to create implied limitations in the claims and only the actual wording of the claims should be considered against these references.

Respectfully submitted,



Tomas H.F. Friend  
Registration No. 54,789  
CFD Research Corporation  
Customer No. 53371

AGENT FOR APPLICANT

Tomas H.F. Friend  
CFD Research Corporation  
215 Wynn Drive, Suite 501  
Huntsville, AL 35805  
256.726.4955